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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,954	03/30/2001	David W. Cannell	05725.0637-00	7371

22852 7590 06/17/2002

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1300 I STREET, NW
WASHINGTON, DC 20005

EXAMINER

WILLIS, MICHAEL A

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 06/17/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/820,954

Applicant(s)

CANNELL ET AL

Examiner

Michael A. Willis

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) 1-36, 40, 42, 44-46, 50-57, 59, 64 and 65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-39, 41, 43, 47-49, 58, 60-63 and 66-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's response of 12 March 2002 is entered. Claims 1-72 are pending.

Election/Restrictions

1. Applicant's election with traverse of Group II: claims 37-72 in Paper No. 7 is acknowledged. The traversal is on the grounds that a proper search for either Group I or II may not yield references such as Williams et al (US Pat. 5,679,344) directed at connective tissue repair due to the claimed limitation "for protecting at least one keratinous fiber from extrinsic damage or repairing at least one keratinous fiber following extrinsic damage". This is not found persuasive because the intended use of composition claims is not given patentable weight. Applicant further argues that because Groups I and II are classified in the same class and subclass, a search for these groups will substantially, if not completely, overlap. This is not persuasive because the search also includes non-patent literature. Claims 1-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

2. Applicant's election with traverse of a) glucosamine as the species of C5-C7 saccharide substituted with at least one amino group and b) xylose as at least one additional sugar in Paper No. 7 is acknowledged. The traversal is on the grounds that the Examiner has failed to show that any burden exists in examining all of the alleged species. However, a serious burden to examine the full scope of the claimed invention exists due to the vast number of compounds encompassed by applicant's claims and

the various permutations in combining those compounds. Claims 40, 42, 44-46, 50-57, 59, and 64-65 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made FINAL. Claims 37-39, 41, 43, 47-49, 58, 60-63, and 66-72 are examined.

Specification

3. The disclosure is objected to because of the following informalities: On page 8, the specification includes a brief description of the drawing. However, no drawing is present in the application. Therefore, either a drawing should be submitted, or lines 5-11 on page 8 should be removed.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 37-39, 41, 43, 47-49, 58, 60-63, and 66-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 37 and 71 are rejected due to the phrase "wherein said at least one compound is present in an amount effective to protect said at least one keratinous fiber from said extrinsic damage or to repair said at least one damaged keratinous fiber". It is

confusing because the amount of protection or repair is unspecified such that any amount of claimed compound would appear to meet the limitation.

7. Claim 38 is rejected due to the phrase "heat-activated". It is unclear what is meant by the phrase. The specification describes a "heat-activated" composition as one that protects or repairs keratinous fiber better than the same composition which is not heated during or after application of the composition. However, does the phrase require a chemical change in the composition following heating? If so, what is the nature of the chemical change?

8. Claims 62 and 72 are rejected due to the term "derivatives". While the specification gives examples of such derivatives, including Schiff bases and hemiketals, the metes and bounds of the term are not disclosed (see specification, page 17). For example, carbon dioxide can be obtained from the chemical degradation of sugar. Is carbon dioxide within the boundaries of a sugar derivative? One of ordinary skill in the art would not be informed of the scope of the invention due to the term "derivatives".

9. Any remaining claims are rejected for depending from an indefinite base claim.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

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(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

11. Claims 37-39, 41, 43, 47-49, 58, and 69-71 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Williams et al (US Pat. 5,679,344). Williams discloses compositions comprising glucosamine. The compositions further comprise ascorbic acid (vitamin C; see claim 4). While the compositions of Williams are intended for the treatment of joint and connective tissue disease, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). A preamble is generally not accorded any patentable weight where it merely recites the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the structural limitations are able to stand alone. See MPEP § 2111.02. With respect to the claimed limitation of "wherein said at least one compound is present in an amount effective to protect or to repair..", it is unclear how much protection or repair is required to meet the limitation. Therefore, the broadest reasonable interpretation is that since Table 5 of the specification show that glucosamine has the capacity to protect or repair hair, therefore, any amount of glucosamine is an effective amount to some degree.

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12. Claims 37-39, 41, 43, 47-49, 58, 60-61, 63, and 68-71 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Noel (US Pat. 5,141,964). Noel discloses cosmetic compositions comprising glucosamine (see abstract). The intended use of the claimed invention is not given patentable weight. The preferred amount of glucosamine is 0.2 to 5% by weight (see col. 1, lines 54-58). Cosmetic forms including creams, emulsions, and liquids are disclosed (see col. 2, lines 43-47). A variety of additives, including antioxidants, are disclosed (see Examples 1-9).

13. Claims 37-39, 41, 43, 47-49, 58, 60-63, and 66-72 are rejected under 35 USC 102(e) as being anticipated by Heisey et al (WO 01/93831). Heisey discloses low carbohydrate compositions and kits thereof (see title). The compositions contain a chondroprotective agent which is most preferably glucosamine (see abstract and page 7, lines 9-10). The amount of chondroprotective agent is most preferably 0.01 to 1% in solution (see page 7, lines 16-19). The compositions further comprise a sweetening agent such as xylose (see page 12, lines 12-15; and claim 5). The sweetening agent is most preferable used in solution at 0.25-5% by weight (see page 14, lines 4-7). The compositions further comprise such ingredients as colorants or preservatives (see page 14, last paragraph). Kits are also disclosed (see pages 30 and 31).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claims 37-39, 41, 43, 47-49, 58, 60-63, and 66-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heisey et al (WO 01/93831). Heisey teaches low carbohydrate compositions and kits thereof (see title). The compositions contain a chondroprotective agent which is most preferably glucosamine (see abstract and page 7, lines 9-10). The amount of chondroprotective agent is most preferably 0.01 to 1% in solution (see page 7, lines 16-19). The compositions further comprise a sweetening agent such as xylose (see page 12, lines 12-15; and claim 5). The sweetening agent is most preferable used in solution at 0.25-5% by weight (see page 14, lines 4-7). The compositions further comprise such ingredients as colorants or preservatives (see page 14, last paragraph). Kits are also disclosed (see pages 30 and 31). The reference lacks a reduction to practice of actual compositions comprising glucosamine and xylose.

17. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the compositions as taught by Heisey to actually reduce to practice a composition of glucosamine and xylose in order to formulate a composition as taught by Heisey. In other words, Heisey teaches the combination of a

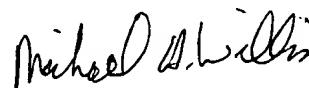
chondroprotective agent and a sweetening agent, where glucosamine is a preferred chondroprotective agent and xylose is an acceptable sweetening agent. Therefore, it would be obvious to make such a combination.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael A. Willis whose telephone number is (703) 305-1679. The examiner can normally be reached on alternate Mon. and Tues. to Fri. from 9am-6:30pm.

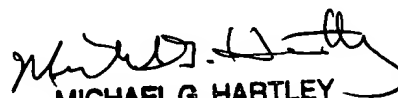
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.



Michael A. Willis
Examiner
Art Unit 1617

June 7, 2002



MICHAEL G. HARTLEY
PRIMARY EXAMINER